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09/786,034	04/23/2001	Gerardo Castillo	PROTEO.P07CI3	4033
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Patrick M Dwyer			ROYDS, LESLIE A	
Proteo Tech Inc			ART UNIT	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/786,034

Applicant(s)

CASTILLO ET AL.

Examiner

Leslie A. Royds

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### **Claims 20-25 are presented for examination.**

Applicant's Amendment filed June 21, 2007 has been received and entered into the present application.

Claims 20-25 remain pending and under examination.

Applicant's arguments, filed June 21, 2007, has been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 20, 22 and 24 remain rejected under 35 U.S.C. 102(e) as being anticipated by Hastings et al. (U.S. Patent No. 6,224,871; Issued 2001, Filed March 1998), already of record, for the reasons of record set forth at pages 2-4 of the previous Office Action dated March 29, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that Hastings et al. discloses ashwangandha (*Withania somnifera*), commonly known as Indian ginseng. Applicant alleges that, even though the instant specification fails to define the type of ginseng to be used, one would look to the plain dictionary meaning of the word, which Applicant asserts is defined as plants belonging to the genus *Panax*.

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Applicant further submits that Indian ginseng is a member of the nightshade or *Solanaceae* family and is not a member of the ginseng *Panax* genus, and, therefore, Hastings et al. fails to teach the claimed invention.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, in the absence of any evidence supportive of Applicant's allegation that the plain dictionary meaning of ginseng is solely limited to plants belonging to the *Panax* genus and does not include the Indian ginseng of the Hastings et al. reference, Applicant's assertions that the claims exclude the Indian ginseng of the reference because such ginseng is obtained from a different genus of plants are not persuasive. Such statements amount to no more than allegations without factual support that the ginseng of the reference is different than, and, thus, not included within the scope of, the instantly claimed invention. Please see, e.g., MPEP §716.01(c)[R-2](II), which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)."

However, even if Applicant had provided evidence supportive of this assertion, it is further noted that the claims do not recite this feature that the ginseng must be derived from a plant belonging to the *Panax* genus. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please reference *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is well established in patent law that the specification teaches an invention, but the claims define the right to exclude. *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 [227 USPQ 577] n.14 (Fed. Cir. 1985).

Additionally, Applicant has failed to provide *any* definition as to the type and derivation of the ginseng intended for use in the presently claimed composition in the instant specification. In fact, Applicant has even admitted so on the record. Please see page 2 of Applicant's remarks, which states,

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"Ginseng is not defined in the specification of the pending application...". As a result, the broad recitation of "ginseng" in the instant claims is inclusive of ginseng of any type, including the Indian ginseng of Hastings et al., absent factual evidence to the contrary, and further absent any specific exclusion in the claims.

Accordingly, it is maintained that Hastings et al. teaches the invention as claimed in present claims 20, 22 and 24 for the reasons set forth *supra* and for those already of record at pages 2-4 of the previous Office Action dated March 29, 2007.

For these reasons, and those already of record at pages 2-4 of the previous Office Action dated March 29, 2007, rejection of claims 20, 22 and 24 remains proper and is **maintained**.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (U.S. Patent No. 6,224,871; Issued 2001, Filed March 1998) in view of Hsia et al. (U.S. Patent No.

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5,976,548; Issued 1999, Filed 1997), each already of record, for the reasons of record set forth at pages 4-6 of the previous Office Action dated March 29, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that neither Hastings et al. nor Hsia et al. should be considered analogous and do not support an obviousness rejection. Applicant relies upon *In re Oetiker* in support of this conclusion, stating that, to be considered analogous, the art must relate to the field of the Applicant's endeavor or be pertinent to the particular problem with which the inventor is concerned. Applicant submits that Hastings and Hsia are directed to the development of formulations of improving joint health etc. and are unrelated to the treatment of amyloidosis as presently claimed.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

Regarding the citation of *In re Oetiker*, Applicant is reminded that *Oetiker* concluded that prior art references relied upon as a basis for rejecting an invention claimed in an application must either be in the field of Applicant's endeavor or, if not, be *reasonably* pertinent to the particular problem with which the inventor was concerned. *Oetiker* cautioned against the combination of elements from non-analogous sources in a manner that reconstructs Applicant's invention by solely relying upon the benefit of hindsight provided by Applicant's disclosure. However, in the instant case, Hastings et al. and Hsia et al. are clearly pertinent to Applicant's field of endeavor, namely, combining the specifically claimed elements into a pharmaceutical composition.

Though the instant rejection is predicated on the finding that one of skill in the art would have been motivated to combine the elements as taught by Hastings et al. and Hsia et al. in order to arrive at a composition comprising the claimed elements for improving joint health and not specifically for the treatment of amyloidosis, it is first noted that the intended use of the combined elements fails to impart any material or physical property to the presently claimed composition that would not have been present

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in the combination suggested by the prior art. In other words, although the art may suggest the same combination of compounds, albeit for a different use stated in the instant claims, such does not change the fact that the same combination of elements as presently claimed into a pharmaceutical composition would have been *prima facie* obvious in view of what was known in the art at the time of the invention.

In making such a combination, the skilled artisan would have necessarily considered the prior art generally available at the time of the invention regarding the claimed elements, uses of the claimed elements and reasons or suggestions to combine such elements to achieve at least additive therapeutic effects. Though the cited references suggest the combination of claimed elements for use in improving joint health, which differs from Applicant's claimed intended use for treating amyloidosis, the fact that Applicant has recognized another therapeutic advantage (i.e., treatment of amyloidosis) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise have been obvious and the combination would have been made for another valid reason (i.e., improving joint health). Please see *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The fact that the prior art does not disclose their use in treating amyloidosis is irrelevant because the combination of such elements would have naturally commended itself to one of ordinary skill in the art at the time of the invention, regardless of the intended use of such components. Moreover, in view of the fact that products of identical composition cannot have mutually exclusive properties (see MPEP §2112), whatever effect(s) this same combination of compounds has on amyloidosis must necessarily be present in the composition suggested by the prior art, absent factual evidence to the contrary.

Accordingly, Applicant's allegations that the cited prior art should be considered non-analogous to the presently claimed invention are not persuasive. The references to Hastings et al. and Hsia et al. are properly considered relevant and would have naturally been considered by one of ordinary skill in the art due to the fact that they are clearly pertinent to pharmaceutical compositions comprising elements

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identical to those presently claimed. Furthermore, it is noted for the record that references may be cited that do differ from Applicant's specific field of endeavor, so long as they would have logically commended themselves to an inventor's attention in considering his problem because of the matter with which they deal. This conclusion is supported by the MPEP at §2141.01(a)[R-2], which states, "The Examiner must determine what is 'analogous prior art' for the purpose of analyzing the obviousness of the subject matter at issue. 'In order to rely on a reference as a basis for rejection of an Applicant's invention, the reference must either be in the field of Applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.' ... *'A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.'*" (emphasis added)

For these reasons, and those already of record at pages 4-6 of the previous Office Action dated March 29, 2007, rejection of claims 20-25 remains proper and is **maintained**.

### ***Double Patenting***

#### **Obviousness-Type Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-25 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, 10-13 and 44-55 of U.S. Patent



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Application No. 10/610,346, already of record, for the reasons of record set forth at pages 8-10 of the previous Office Action dated March 29, 2007, of which said reasons are herein incorporated by reference.

Applicant states that a terminal disclaimer will be timely filed once allowable subject matter is indicated.

In view of the fact that allowable subject matter has not been identified in the instant case, and further in the absence of a Terminal Disclaimer or remarks to the contrary, the obviousness-type double patenting rejection remains proper and is herein **maintained**.

#### *Conclusion*

Rejection of claims 20-25 remains proper and is **maintained**.

No claims of the present application are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

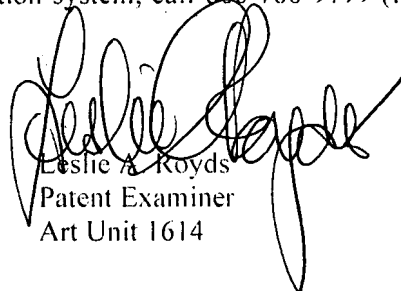
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie A. Koyds  
Patent Examiner  
Art Unit 1614

September 5, 2007



ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER